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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/886,779 06/21/2001 Chandran R. Sabanayagam 701586/50113-C 6933

26248 7590 11/06/2002

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[REDACTED] EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 11/06/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/886,779	SABANAYAGAM ET AL.
Examiner	Art Unit	
Frank W Lu	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 19 August 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 11 and 23-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 11 and 23-33 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 21 June 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> .	6) <input type="checkbox"/> Other: _____

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DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on August 19, 2002 has been entered as Paper No:7. The claims pending in this application are claims 11 and 23-33. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn.

Claim Objections

2. Claim 30 is objected to because of the following informalities: "each said oligonucleotides" should be "each said oligonucleotide".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 is rejected as vague and indefinite in view of the phrase "extending from each said oligonucleotides along a Z coordinate a plurality of unique circular DNA templates, each circular DNA template comprising a sequence of interest, wherein each said circular DNA template is hybridized to each said oligonucleotides by a region complementary to at least a

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portion of said sequence of said oligonucleotides" because it is unclear what it intended. For example, does this phrase mean that a plurality of unique circular DNA templates, each circular DNA template comprising a sequence of interest, wherein each said circular DNA template hybridizes to each said oligonucleotides by a region complementary to at least a portion of said sequence of said oligonucleotides and extends from each said oligonucleotide along a Z coordinate in the presence of a polymerase in the rolling circle amplification or this phrase mean something else? From the claim, it is also unclear whether amplified product of a plurality of unique circular DNA templates are the compositions of an ordered redundant array or not. Please clarify.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 11 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Caviani Pease *et al.*, (Proc. Natl. Acad. Sci. USA, 91, 5022-5026, 1994).

Caviani Pease *et al.*, teach a light-generated oligonucleotide array. For example, see abstract in page 5022 and Figure 4 in page 5025. Although Caviani Pease *et al.*, did not show an

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ordered redundant array of immobilized oligonucleotides produced by the method recited in claims 11 or 23, it was well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product did not depend on its method of production. If the product in the product-by-process claim was the same as or obvious from a product of the prior art, the claim would be unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Therefore, Caviani Pease *et al.*, teach all limitations recited in claims 11 and 23.

Response to Arguments

In page 3, last paragraph of applicant's remarks, applicant argued that "the ordered array of Caviani Pease et al., does not in any way teach an array wherein there are at least two or three copies and certainly not 10 or 50 copies of the sequence of interest extending in the Z dimension".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. First, even through step (d) in claims 11 and 23 has a phrase "wherein said ordered redundant array refers to said array having at least two copies of said sequence of interest along the z coordinate", step (a) to (d) are the method steps to make an ordered redundant array. From the claims, it is unclear what is in the array. Therefore, any kind of art that teaches an oligonucleotide array such as the reference taught by Caviani Pease *et al.*, read claims 11 and 13. Note that it was well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product did not depend on its method of production. If the

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product in the product-by-process claim was the same as or obvious from a product of the prior art, the claim would be unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

7. Claims 11 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Chetverin *et al.*, (US Patent 6,103,463, filed on May 23, 1994).

Chetverin *et al.*, teach ordered arrays of oligonucleotides immobilized on a solid support. For example, see columns 1 and 44, and Figure 1. Although Chetverin *et al.*, did not show an ordered redundant array of immobilized oligonucleotides produced by the method recited in claims 11 or 23, it was well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product did not depend on its method of production. If the product in the product-by-process claim was the same as or obvious from a product of the prior art, the claim would be unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Therefore, Chetverin *et al.*, teach all limitations recited in claims 11 and 23.

Response to Arguments

In page 4, third paragraph of applicant remarks, applicant argued that "[T]he ordered array described in Chetverin, while referring to a variable and constant region (see Figure 1A and the accompanying text), does not teach or require that said array must contain at least two copies of the sequence of interest extending in the Z dimension.".

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This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. First, even through step (d) in claims 11 and 23 has a phrase "wherein said ordered redundant array refers to said array having at least two copies of said sequence of interest along the z coordinate", step (a) to (d) are the method steps to make an ordered redundant array. From the claims, it is unclear what is in the array. Therefore, any kind of art that teaches an oligonucleotide array such as the patent taught by Chetverin *et al.*, read claims 11 and 13. Note that it was well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product did not depend on its method of production. If the product in the product-by-process claim was the same as or obvious from a product of the prior art, the claim would be unpatentable even though the prior product was made by a different process. "*In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

8. Claims 11 and 23-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Lizardi *et al.*, (US Patent No. 6,143,495, priority date: November 21, 1995).

Lizardi *et al.*, teach rolling circle amplification.

Regarding claims 11, 23, and 30, up to 256 individual target or assay samples arranged in dots in a glass slide. Each solid-state sample could be an identical set of sample dots, and ligation mediated rolling circle amplification were carried out using a different set of open circle probes and gap oligonucleotides, collectively referred to as a probe set, for each solid-state sample (see column 49 and Figure 8). Note that: (1) claims 11 and 23 were read as an oligonucleotide array

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since the method of making in the claims was not considered as a part of the product as recited in claims 11 and 23. Note that it was well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product did not depend on its method of production. If the product in the product-by-process claim was the same as or obvious from a product of the prior art, the claim would be unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985); (2) identical set of sample dots in the glass slide was considered to be a plurality of identical oligonucleotides immobilized on the substrate as recited in claims 11, 23, and 30; (3) although Lizardi *et al.*, did not directly show that each identical set of sample dot comprising target defined by x and y coordinates as recited in claims 11, 23, and 30, this limitation was considered to be inherent to the reference taught by Lizardi *et al.*, since each identical set of sample dot comprising target had its own x and y coordinates; (4) a different set of open circle probes was be considered to have different sequences of interest as recited in claims 11, 23, and 30; and (5) since, from the claim, it was unclear whether amplified products of a plurality of unique circular DNA templates were the compositions of an ordered redundant array or not (see above rejection under 35 USC § 112), the phrase "wherein said circular template creates an extended immobilized oligonucleotide comprising at least two copies of said sequence of interest" was considered as optional.

Regarding claims 24-29, claims 24-29 were read as an oligonucleotide array with 3-50 copies sequences of interest because the method of making in the claims was not considered as a part of the product as recited in claims 11 and 23. Although Lizardi *et al.*, did not directly to

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teach to extend amplified nucleic acid in a rolling circle amplification in a Z dimension, any kind of direction that amplified nucleic acid was extended to during rolling circle amplification was considered to Z dimension.

Regarding claims 31-33, since, from the claim, it was unclear whether amplified products of a plurality of unique circular DNA templates were the compositions of an ordered redundant array or not (see above rejection under 35 USC § 112), the limitations in claims 31-33 was considered as optional.

Therefore, Lizardi *et al.*, teach all limitations recited in claims 11 and 23-33.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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10. No claim is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
October 29, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600